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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,009	12/11/2001	Tore Curstedt	211596US0PCT	5055
22850	7590	12/06/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			TELLER, ROY R	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 12/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/926,009

Applicant(s)

CURSTEDT ET AL.

Examiner

Roy Teller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 17-19, 21, 22 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 17-19, 21-22, and 28-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This office action is in response to the amendment, received 6/18/04.

Claims 1-13, 17-19, 21-22, and 28-32 are pending.

Claim 32 is drawn to a method of treatment. The restriction requirement elected group I, an SP-C analog. Claim 32 is drawn to a non-elected invention and is withdrawn.

New Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13, 17-19, 21-22, and 28-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:2, does not reasonably provide enablement for an SP-C analog having the general formula (I) SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue

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experimentation. The factors include:

- 1) the nature of the invention;
- 2) the breadth of the claims;
- 3) the predictability or unpredictability of the art
- 4) the amount of direction or guidance presented;
- 5) the presence or absence of working examples;
- 6) the quantity of experimentation necessary;
- 7) the state of the prior art; and,
- 8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

The claimed invention is drawn to an SP-C analog of SEQ ID NO:1

The breadth of the claims is excessive with regard to claiming an SP-C analog of SEQ ID NO:1.

Applicant has only provided a complete formula of SEQ ID NO:2 . Applicant have provided no guidance comprising the undefined sequence of SEQ ID NO: 1. It would not be predictable to the artisan which amino acids comprising an SP-C analog of SEQ ID NO:1 would work in the present invention.

In consideration of these factors, it is apparent that there is undue experimentation because of a variability in prediction of outcome that is not addressed by the present application.

Absent factual data to the contrary, the amount and level of experimentation needed is undue to practice the invention as claimed.

Claim Rejections - 35 USC § 102

Claims 1 and 7 stand rejected under 35 U.S.C. 102(b) as being anticipated by Benson, WO 91/18015 for reasons of record which are restated below.

The claimed invention is drawn to a SP-C analog, for a method of treating surfactant deficiency comprising administering the SP-C analog, wherein the surfactant deficiency is respiratory distress syndrome.

Benson beneficially teaches various derived peptides have alveolar surfactant protein (ASP) activity which are useful in the management of certain respiratory diseases, see abstract. Benson teaches a purified polypeptide having ASP activity, see claims 1 and 8.

Therefore, the reference is deemed to anticipate the instant claims above.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Applicant contends that the '015 reference polypeptide is structurally different than those encompassed by the present claims. Applicant points to the "B" amino acid residues (K, W, F, Y, and Orn) between residues 35 and 51 that the '015 reference does not have. However, the examiner contends that claim 8 of the '015 reference does contain the K and F amino acids between residues 35 and 51.

Claim Rejections - 35 USC § 103

Claims 1 and 7 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Benson, WO 91/18015 for reasons of record which are restated below.

The claimed invention is drawn to a SP-C analog, for a method of treating surfactant deficiency comprising administering the SP-C analog, wherein the surfactant deficiency is respiratory distress syndrome.

The reference is relied upon for the reasons discussed *supra*.

From the teaching of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in absence of evidence to the contrary.

Applicant contends that the '015 reference polypeptide is structurally different than those encompassed by the present claims. Applicant points to the "B" amino acid residues (K, W, F, Y, and Orn) between residues 35 and 51 that the '015 reference does not have. However, the examiner contends that claim 8 of the '015 reference does contain the K and F amino acids between residues 35 and 51.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CHRISTOPHER R. TATE
PRIMARY EXAMINER